

HTAi 2016 Conference
Informing Health Care Decisions with Values and Evidence
Pre-Conference Workshop Report – Draft to participants

Setting priorities for the new HTAi Interest Group on Vaccines HTA

Tuesday 10 May 2016, 9.00am-12.30pm
Keio Plaza Hotel, Tokyo

Speakers

Karen Facey (facilitator/notes), W Ricciardi, A. Rappagliosi, Lars Sandman, Marco Marchetti, Christelle Saint Sardos (notes)

Participants (~25):

Countries of origin: Japan, Taiwan, China, Australia, Thailand, Europe (Bulgaria, Czech Republic, Netherlands, Denmark, Sweden, Italy, UK, France).

Occupation: HTA officers, Academics, Industry, Public Health, consultants

Workshop objectives

- To agree the scope of an HTAi Interest Group on Vaccines HTA
- To develop a workplan with associated resource requirements
- To initiate a governance structure for the Interest Group

Introductions by Karen Facey

Karen gave an overview of the panel that had been held about vaccines HTA at the HTAi conference last year. She explained how this had led to a submission to HTAi to establish a new Interest Group (IG) on Vaccines HTA that was supported by a wide range of HTAi members in different disciplines and across the world from Canada, to Europe and New Zealand. The IG had been conditionally approved and interested parties were asked to develop a workplan for the Interest Group and consider the resources required.

Brief Notes of Presentations to Set the Scene – See slides for full details

What's special about vaccines? - Walter Ricciardi

- Need to consider determinants of vaccine hesitancy, and what makes it difficult to handle for scientists.
- Vaccine hesitancy matters for individual and communities;
- Current outbreaks have occurred due to sub optimal immunization coverage
- We have “a perfect storm” - tough economic realities (pressure on budgets) and healthcare realities (ageing population)
- Healthcare reforms are now considering sustainability as the low-hanging fruits have been picked.
- In the vaccine field, we need to make the best choices, especially to tackle vaccine hesitancy. Evaluation is needed to choose the best strategies to increase coverage. HTA has a role here.

Customization of vaccines' HTA to optimize immunization policies and vaccines' supply - Andrea Rappagliosi

Only measuring vaccine effectiveness is not enough, as the intervention is composed of the vaccine and the programme: there is a need for methodologies that measure what is an effective programme.

HTA can help immunization policies by ensuring that:

1. HTA methodology assesses the value of vaccination programmes
2. Vaccine's purchasing is based on HTA (sustainability)
3. There is improved coordination of vaccines assessment

There is an EU political momentum: HTA is one of the pillars of the EU Council Conclusions and this should be built upon.



EUnetHTA: what role for vaccines? K. Facey on behalf of F. Meyer

One of EUnetHTA's first activities was to share HPV assessment reports and Joint Action 2 (JA2) undertook a rapid relative effectiveness assessment of a therapeutic vaccine in herpes zoster (in which there were no herd immunity issues).

Vaccines' assessment differs from country to country. In some jurisdictions, HTA informs decision makers, in others there are national advisory groups that are specific to vaccines (called National Immunization Technical Advisory Groups – NITAGs, in Europe).

Differentiate between assessment elements that can be shared across jurisdictions and those that are context specific that need to be handled at local level. This should be done in the context of the H2020.

Consider the implications for Early Dialogue as some NITAGs involved in EMA parallel advice.

Post-launch evidence generation is particularly important for vaccination programmes and will be a key strand of EUnetHTA JA3.

Healthcare expenditure on prevention in the spending review era. Marco Marchetti

In Italy, the budget dedicated to vaccines is less than 6% of healthcare expenditure.

Literature review performed on the cost-effectiveness of vaccination in Italy compared to other areas of prevention (cancer, cardiovascular). Probabilistic sensitivity analysis show that there is a 0.9 (90%) chance that vaccines are cost-effective at our usual threshold; 100% for hepatitis B. There is 100% chance that vaccination is below 30,000€/Quality Adjusted Life Year threshold.

In the cardiovascular prevention field, cost-effectiveness is 70%, whereas cancer prevention is 100% cost-effective. Probability of screening cost effectiveness is 0.8.

Conclusion: these results show that investments in prevention are good value for money and can contribute to the overall efficiency of the health care system. In this context,

achieving the 5% ceiling of the funding for prevention should be a priority for policy makers.



Ethical Assessment in HTA. Lars Sandman

The EUnetHTA HTA core model® has several adaptations (diagnostics, screening etc): do we need one for vaccines?

Several generic tools exist for ethical assessment in HTA, but as there are specific issues that are relevant to vaccines assessment, it is interesting to consider whether these tools are appropriate for vaccines assessment.

There are specific ethical issues for vaccines: e.g. different groups get the potential benefits and harms; vaccination for the benefit of other groups; mandatory vaccinations; vaccine hesitancy/resistance-how to deal with this? Collective need vs individual need. Legislation: how to deal with narcolepsy cases related to swine flu?

These issues suggest that we need specific tools for ethical assessment of vaccines, which could be adapted for different types of vaccines.



Guidelines for vaccines' assessment and the gaps. Karen Facey

Social Issues

Jackie Street of the HTAi Citizen and Community Working group has suggested a range of social issues that uniquely feature in vaccination programmes, including the consideration of risks and benefits when the individual is contributing to herd immunity, including issues of cocooning, parental consents for babies, teenagers choice, privacy, welfare disincentives, funding of vaccines to prevent behaviours the society is not keen to accept, etc. All these need to be explored and understood to consider what leads to “hesitancy” and how it might be addressed.

Economic issues

A group of EU economists in HTA agencies and academia have published detailed guidelines on economic evaluations of vaccination programmes (Ultsch et al, 2015). It would be helpful to check that they are applicable internationally.

Assessment framework

Piso et al 2011 presented a Delphi study to develop consensus on the key assessment elements of vaccination programmes. A limited number of responses were received from Australia, EU, Canada and US and it was indicated that the framework for assessment needs to be tested more widely in an international community. HTAi could further develop this work, bringing the more international perspective.



Discussion with speakers

Question 1: different types of vaccination (short term as Flu, Long term as HPV) => which one should be the focus of the IG?

LS: The form and objective of the vaccination programme is critical from an ethics perspective, but there is no need for specific tool for different forms of vaccination programmes.

AR: In Flu for example, what is most important beyond the vaccine is to have a very effective programme, in order to capture the full outcome of vaccination

Question 2: Will there be early dialogue (or parallel scientific advice) for vaccines?

WR: given the complex nature of vaccines they are ideal for full HTA, including ethical and social issues. There is a need for specific tools for vaccines' HTA, which could be delivered under the auspices of HTA, given its policy focus.

Mondher Toumi: Vaccines would be good candidates for Early Dialogue or PSA but would be good to involve NITAGs as well.

Question 3: How do you incentivize vaccine development given the long development pathway (15y development + 6 year access timelines in EU) and the variability in economic guidelines (herd immunity concept not accepted in some HTAs, which required development of RWE).

KF: There is a need standardization and avoidance of duplication. So guidelines are needed that will be implemented. The economic guidelines from Europe cover many issues; it will be interesting to see if these could be accepted more widely. ISPOR has a taskforce developing guidelines for economic evaluation of vaccines, so we should link into that. It is important to recognize that vaccination programmes are complex and need full HTA, not just economic evaluation.

Group discussion on creating an HTAi IG for Vaccines HTA

IG Scope

- HTA for vaccination programmes (not simply the vaccine product)
- Prevention is focus, but connection with therapeutic vaccination should be made
- **So name is HTAi Interest Group for Assessment of Vaccination Programmes**

IG Objective

Develop a specific HTA decision framework for vaccines, including public health priorities (policy, not economics..)

Collaborations for the IG

<u>Agencies</u> HTA bodies EUnetHTA National immunization agencies INAHTA CDC ECDC WHO	<u>Scientific Societies</u> EUPHA ISPE IUPHAR
<u>Stakeholders</u> Patient groups Consumers Industry associations Innovative medicines initiative Decision makers	<u>Researchers</u> HTAi IGs on Ethics, Patient/Citizen Involvement, Developing Countries ISPOR Taskforce on vaccine economic evaluation Academia

IG Priorities

- Facilitate discussion of all relevant parties about assessment issues relating to vaccination programmes (including those outside HTA)
- Share experiences on vaccines' assessment internationally, listing critical issues with vaccines in the policy context, different players (NiTAG vs HTA), create a map of what's happening
- Consider whether EUnetHTA JA3 could undertake a joint assessment of a preventative vaccine
- Develop and publish a position paper on the critical issues on vaccines HTA and decision making
- Create a themed section of IJTAHC Position paper, ethical Check list, social issues.
- Create an agreed HTA evaluation framework for vaccination programs (an international state of the art); with terms and definitions identified for the HTAi HTA glossary; cover issues relating to effectiveness, uncertainty, programmatic issues, population/herd effect, social and ethical issues

It was noted that HTAi has few resources but that this work would be done in-kind by members of the Interest Group. HTAi could facilitate important interdisciplinary working and open up links to important stakeholders such as WHO.

Post-meeting activity suggestion

CIMULACT (www.cimulact.eu) will organise the 3rd European Technology Assessment Conference in Dublin in May 2017 with a theme of "New technologies and societal challenges: Bridging the worlds of science, society & policy making". Its ethos seems to be the wide ranging kind of assessment approach discussed. Deadlines for submissions of sessions is 31 July 2016 <http://cork2017.technology-assessment.info/call-for-sessions>.

Next steps

- Workshop report submitted to HTAi board for full IG approval.
- Interested individuals asked if they want to join the IG Steering Committee (Toumi, Jerabkova, Zhang, Nymark already agreed)
- Governance arrangements to be put in place
- Workplan to be agreed with all interested parties